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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

KEREN DIMAS, an individual.

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER OY; BAYER PHARMA AG; DOES 1-10.

Defendants.

Case No.

COMPLAINT FOR:

(1) DEFECTIVE MANUFACTURING
(2) DESIGN DEFECT
(3) NEGLIGENCE
(4) FAILURE TO WARN
(5) STRICT LIABILITY
(6) BREACH OF IMPLIED WARRANTY
(7) BREACH OF EXPRESS WARRANTY
(8) NEGLIGENT MISREPRESENTATION
(9) FRAUDULENT MISREPRESENTATION
(10) FRAUD BY CONCEALMENT

JURY TRIAL DEMANDED

INTRODUCTION

Plaintiff KEREN DIMAS ("Plaintiff"), by and through their undersigned attorneys, hereby bring this action against the defendant, Bayer Healthcare Pharmaceuticals, Inc. ("Bayer") for personal injuries suffered as a proximate result of Plaintiff's use of the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Bayer.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have principal places of business in states and/or foreign states other than the states in which the Plaintiff reside.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to at least some of Plaintiff's claims occurred, in part, in the Eastern District of California and because Defendants transact business in this district.

PARTIES AND CITIZENSHIP

1. Plaintiff KEREN DIMAS is a natural person and a resident and citizen of West Sacramento, California, county of Yolo.

2. Defendant Bayer Healthcare Pharmaceuticals Inc. (BHCP), is a

corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Defendant Bayer Healthcare Pharmaceuticals, Inc., can be served with process through its registered agent for service of process in California, Corporation Service Company, 2710 Gateway Oaks Dr, Suite I50N, Sacramento, California 95833.

3. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

4. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

5. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application (NDA) for contraceptive device Mirena®.

6. Foreign Defendant Bayer Oy has its principal place of business in Finland. Bayer Oy can be served with process through its legal representative at Legal Department Panisiontie 47/ P.O. Box 415 20101 Turku Finland.

7. Foreign Defendant Bay Pharma AG has its principal place of business in Germany. Bayer Pharma AG can be served with process through its legal representative located at Muellerstrasse 178, 133353 Berlin Germany.

8. Bayer Oy sold Mirena® directly to BHCP until September 2008. Thereafter, Bayer Oy sold Mirena® to Bayer Pharma AG, which resold to BHCP. Bayer Pharma AG purchased all Mirena® products sold in the United States exclusively from Bayer Oy and resold the product to BHCP.

9. The term Bayer and/or the term Defendants shall mean and refer to BHCP, Bayer Oy and Bayer Pharma AG collectively.

10. Bayer is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system, Mirena®.

11. Bayer does business in California through the sale of Mirena® and other prescription drugs in the state.

12. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

FACTS

13. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

14. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication used as contraceptive.

15. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

16. The system releases levonorgestrel, a synthetic progestrogen, directly into the uterus for birth control. Defendants admit it is not known exactly how Mirena works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

17. The Mirena® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5) years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

18. The package labeling recommends that Mirena® be used in women who have had at least one child.

19. Up until May 29, 2014 when Bayer issued a self-described major change in the Mirena label concerning the risk of perforation, Mirena®'s label did not warn about spontaneous migration of the IUS, but only stated that migration may occur if the uterus is perforated during insertion of the device.

20. Mirena®'s label also describes perforation as an "uncommon" event, despite the numerous women who have suffered migration and perforation post insertion, clearly demonstrating this assertion to be false.

21. Defendants have a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

22. In or around December 2009, Defendants were contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private by a representative from “Mom Central”, a social networking internet site, and Ms. Barb Dehn, a nurse practitioner with Defendants.

23. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®' s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

24. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

25. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on Mirena®.

26. Finally, Defendants falsely claimed that Defendants' product required no compliance with a monthly routine.

PLAINTIFF SPECIFIC FACTS

27. Plaintiff KEREN DIMAS had her physician in California insert the Mirena® IUS.

28. As a result of Plaintiff KEREN DIMAS's use of Mirena® IUS she suffered migration and perforation of the device through her uterus. Plaintiff's Mirena® IUS was surgically removed as a result. Plaintiff KEREN DIMAS continues to suffer from pain and discomfort as a result.

FIRST CAUSE OF ACTION:

DEFECTIVE MANUFACTURING

55. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

56. Defendants were and are engaged in the business of selling Mirena® in the State of California.

57. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants was expected to, and did, reach each of the Plaintiff without substantial change in the condition in which it was sold.

58. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena® outweighs any benefit derived therefrom. The unreasonably dangerous nature of Mirena® caused serious harm to Plaintiff.

59. Defendants manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff.

60. As a direct and proximate result of Plaintiff's use of Mirena®, they were each forced to undergo surgical removal of the IUS, developed severe pain from the device and had to undergo numerous procedures.

61. Defendants placed Mirena® into the stream commerce wanton reckless disregard for the public safety.

62. Defendants knew and, in fact, advertised and promoted the use of Mirena® despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of the Defendants' advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

63. Despite the fact that evidence existed that the use of Mirena® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with the Mirena® and in fact acted to deceive the medical community and public at large, including all potential users of Mirena® by promoting it as safe and effective.

64. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

65. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

66. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION:

DESIGN DEFECT

67. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

68. Defendants were and are engaged in the business of selling Mirena® the State of California.

69. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

70. The foreseeable risks associated with the design or formulation of the Mirena® include, but are not limited to, the fact that the design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

71. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

72. As a direct and proximate cause of Plaintiff's use of Mirena®, she was forced to undergo surgical removal of the Mirena®, developed severe pain, and underwent numerous procedures.

73. Defendants placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety.

74. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

75. There are contraceptives on the market with safer alternative designs that they provide equal or greater efficacy and far less risk.

76. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION:

NEGLIGENCE

77. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

78. Upon information and belief, Defendants failed to use reasonable care in designing Mirena® in that they:

a. failed to properly and thoroughly test Mirena® before releasing the drug to market;

b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Mirena®;

c. failed to conduct sufficient post-market testing and surveillance of Mirena®;

d. designed, manufactured, marketed, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeable occur as a result of using the drug

e. failed to exercise due care when adve11ising and promoting Mirena®; and

f. negligently continued to manufacture, market, advertise, and distribute Mirena® after Defendants knew or should have known of its adverse effects.

79. A reasonable manufacturer would or should have known that its risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

80. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION:

FAILURE TO WARN

81. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

82. Mirena® is a defective and therefore an unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, uterine perforation post-insertion, or the possibility that device complications such as migration and perforation may cause abscesses, infections require surgery for removal and/or may necessitate hysterectomy, oophorectomy, and other complications.

83. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold and otherwise released into the stream of commerce the pharmaceutical, Mirena®, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena®.

84. Mirena® was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

85. Defendants downplayed the serious and dangerous side effects of Mirena® to encourage sales of the product; consequently, Defendants placed its profits above its customers' safety.

86. Mirena® was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert Plaintiff

to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks associated with Mirena®, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

87. Plaintiff used Mirena® as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

88. Plaintiff could not have discovered any defect in Mirena® through the exercise of reasonable care.

89. Defendants, as manufactures of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risk and side effects of Mirena®.

90. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physician(s).

91. Defendants had a continuing duty to warn consumers, including Plaintiff and each of their physicians, and the medical community of the dangers associated with Mirena®, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendant breached their duty.

92. Although Defendants knew, or were reckless in not knowing, of the defective nature of Mirena®, they continued to manufacture, design, formulate, test, package, label, produce, create, made, construct, assemble, market, advertise, distribute and sell Mirena® without providing adequate warnings and instructions concerning the use of Mirena® so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena®.

93. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FIFTH CAUSE OF ACTION:

STRICT LIABILITY

94. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

95. Defendants are manufacturers and/or suppliers of Mirena® and are strictly liable to Plaintiff for manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, advertising, distributing, selling and placing Mirena® into the stream of commerce.

96. Mirena®, manufactured and/or supplied by Defendants, was defective in design or formulation in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

97. Mirena® was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

98. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena® created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendants failed to adequately warn of these risks.

99. Mirena® was defective due to inadequate pre-marketing testing.

100. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or

should have known of the extreme risks associated with Mirena® and continue to promote Mirena® in the absence of those adequate warnings.

101. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all suck other relief as the Court deems appropriate pursuant to the common law and statutory law.

SIXTH CAUSE OF ACTION:

BREACH OF IMPLIED WARRANTY

102. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

103. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® as safe for use by the public at large, including Plaintiff, who purchased Mirena®. Defendants knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

104. Plaintiff reasonably relied on the skill and judgment of the Defendant, and as such their implied warranty, in using Mirena®.

105. Contrary to same, Mirena® was not of merchantable quality or safe or for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

106. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SEVENTH CAUSE OF ACTION:

BREACH OF EXPRESS WARRANTY

107. Plaintiff incorporates by reference all other paragraphs complaint as if fully set forth herein, and further allege as follows:

108. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® were expressly warranted to be safe by Defendants for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which Mirena® was to be used and Defendant warranted Mirena® to be in all respects safe, effective and proper for such purposes.

109. Mirena® does not conform to these express warranties and representations because Mirena® is not safe or effective and may produce serious side effects.

110. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

EIGHTH CAUSE OF ACTION:

NEGLIGENT MISREPRESENTATION

111. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

112. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena®, owed a duty to provide accurate and complete information regarding Mirena®.

113. Defendants falsely represented to Plaintiff that Mirena® was a safe and effective contraceptive option. The representations by Defendants were in fact false, as Mirena® is not safe and is dangerous to the health of its users.

114. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and their health care providers, information about the propensity of Mirena® to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Mirena® despite the lack of information regarding same.

115. These misrepresentations were made by Defendants with the intent to induce Plaintiff to use Mirena®, which caused each of their injuries.

116. At the time of Defendants' misrepresentations and omissions, Plaintiff were ignorant of the falsity of these statements and reasonably believed them to be true.

117. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product. Plaintiff reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Mirena®.

118. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

NINTH CAUSE OF ACTION:

FRAUDULENT MISREPRESENTATION

119. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

120. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® described herein, owed a duty to provide accurate and complete information regarding Mirena®.

121. Defendants fraudulently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm.

122. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff were unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

123. Defendants knew this information to be false, incomplete and misleading.

124. Defendants intended to deceive and mislead Plaintiff so that they might rely on these fraudulent misrepresentations.

125. Plaintiff had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

126. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff s profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

TENTH CAUSE OF ACTION:

FRAUD BY CONCEALMENT

127. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

128. Defendants had a duty and obligation to disclose to Plaintiff that Mirena® was dangerous and likely to cause serious health consequences to users when used as prescribed.

129. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff with the intent to defraud her as herein alleged.

130. Neither Plaintiff nor any of her physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

131. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff have proximately sustained damage, as set forth herein.

132. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff has suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

REOUEST FOR PUNITIVE DAMAGES

133. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

134. At all times relevant herein, Defendants:

a. knew that Mirena® was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Mirena®; and

d. with full knowledge the health risks associated with Mirena® and without adequate warnings of the same, manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® for routine use.

135. Defendant, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the general public.

136. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff have become liable.

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WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants for compensatory, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

DATED: July 2, 2015 KABATECK BROWN KELLNER LLP

By: /s/ Lina B. Melidonian
Lina B. Melidonian
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Respectfully submitted,

DATED: July 2, 2015 KABATECK BROWN KELLNER LLP

By: /s/ Lina B. Melidonian
Lina B. Melidonian
Attorneys for Plaintiff